IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **WAVE 5 CASE LISTED IN EXHIBIT A TO DEFENDANTS' MOTION**	

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE AND ADOPTION OF PRIOR MOTIONS TO EXCLUDE GENERAL-CAUSATION OPINION TESTIMONY OF ROBERT D. MOORE, D.O.

Robert D. Moore, D.O. seeks to offer various opinions regarding the ability of the TVT-O mesh product to cause the injuries alleged by the sole plaintiff—Lynne Scuderi—who designated him as a general-causation expert in Wave 5. *See* Ex. A, Defs.' Case List. Defendants Ethicon, Inc. and Johnson & Johnson (Ethicon) challenged certain of Dr. Moore's opinions in Wave 1 (*see* Defs.' Mot. (Dkt. 2119); Defs.' Mem. (Dkt. 2120)) as being inadmissible under Rules 702 and 403, *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). This Court ruled on those challenges (*see* Ex. B, 9/1/16 Mem. Op. (Dkt. 2715)) and adopted that ruling in subsequent waves (*see* 3/27/17 Mem. Op. (Dkt 3509) (Wave 2); 7/21/17 Mem. Op. (Dkt. 4219) (Wave 3)).

Ethicon adopts its Wave 1 motion and supporting memorandum for the single Wave 5 plaintiff who designated Dr. Moore, but Ethicon also raises the supplemental challenges set forth

below based upon this Court's more recent *Daubert*-related rulings. These include challenges to the following opinions of Dr. Moore:

- **Opinions about what information should be included in the IFU.** Dr. Moore offers several opinions about what the IFU should include, including, among others, that the IFU should include information about the frequency/severity/duration of various complications or conditions. In line with this Court's recent rulings, Dr. Moore has no additional expertise that makes him qualified to opine about what should be included in an IFU. His warnings opinions should be excluded.

- **Opinion that the inside-out surgical technique is a design defect.** Dr. Moore criticizes the inside-out procedure used to implant TVT-O, but that opinion is irrelevant. Though this Court initially reserved judgment on this issue as to Dr. Moore in its earlier rulings, this Court's recent decisions in *Mullins* and as to Dr. Goodyear show that surgical procedures are irrelevant to claims for design defect because a surgical procedure is not a flaw in a product's design.

Ethicon asks that these opinions be excluded for the reasons more fully explained below. In all other respects, Ethicon asks this Court to continue to exclude and/or reserve ruling on Dr. Moore's opinions consistent with its Wave 1 ruling, including excluding his opinions (1) based on "impermissible historical narratives" (Ex. B, 9/1/16 Mem. Op. (Dkt. 2715) at 6-7); (2) as to including frequency/severity/duration information in the IFU (*id*. at 9); and (3) expressing legal conclusions, offering opinion testimony about state of mind, or parroting corporate documents (*id*. at 12-13).

ARGUMENTS AND AUTHORITIES

Ethicon incorporates by reference the standard for *Daubert* motions articulated by this Court in *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *1-3 (S.D.W. Va. July 8, 2014).

I. Dr. Moore is not qualified to opine about what information should be included in an IFU.

This Court has determined that a urogynecologist may testify "about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU," but it has ruled that the very "same expert must possess *additional expertise* to offer expert testimony about what information *should or should not be included* in an IFU." *See, e.g., In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536885, at *2 (S.D.W. Va. Aug. 30, 2016) (emphasis added) (excluding Dr. Margolis's warnings opinions because he "is not an expert in the development of warning labels and thus is not qualified to offer expert testimony about warnings"); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4500767, at *4 (S.D.W. Va. Aug. 26, 2016) (same, as to Dr. Blaivas), among others.

Here, Dr. Moore opines that the IFU for the TVT-O was inadequate because Ethicon did not include information about certain risks. *See* Ex. C, Moore Report at 32-38; *see also* Ex. D, Moore 4/15/16 Dep. Tr. 132:15-133:5, 135:5-17, 137:7-11, 139:14-140:9. But Dr. Moore does not have the "additional expertise" this Court requires to be qualified to give warnings adequacy opinions. Indeed, he has never drafted language for an IFU. Ex. D, Moore 4/15/16 Dep. Tr. 72:13-16. Merely reviewing IFUs as part of his clinical practice (Ex. C, Moore Report at 28) is not enough.

Accordingly, Ethicon respectfully asks the Court to limit Dr. Moore to testifying about whether specific risks appeared in the IFU and preclude him from testifying about whether other risks "should or should not be included in an IFU." *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4536885, at *2. This includes his opinion that the IFU should have included information about the frequency/severity/duration of various risks. *See* Ex. D, Moore 4/15/16 Dep. Tr. 132:24-133:5. As this Court has already determined, this opinion is also

independently excludible because it is nothing more than Dr. Moore's *ipse dixit* and unreliable for that reason as well. *See* Ex. B, 9/1/16 Mem. Op. (Dkt. 2715) at 9.

II. Dr. Moore's criticism of the inside-out surgical technique is irrelevant because a *surgical procedure* is not a *product design* for purposes of proving a claim for design defect.

Ethicon previously challenged Dr. Moore's opinions about the inside-out surgical technique used to implant TVT-O, arguing that the surgical technique was irrelevant to plaintiffs' claims for design defect because criticisms of a *surgical technique* do not identify a defect in the *product's design*. *See* Defs.' Mem. (Dkt. 2120) at 9-10. Although this Court reserved judgment (*see* Ex. B, Mem. Op. (Dkt. 2715) at 8), this Court has since rejected plaintiffs' attempts to introduce evidence equating a surgical procedure with a product's design (*Mullins v. Johnson & Johnson*, No. 2:12-cv-02952, 2017 WL 711766, at *2 (S.D.W. Va. Feb. 23, 2017) (holding that evidence to prove a claim for design defect "must be examined in the context of products—not surgeries or procedures"); *accord In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2017 WL 1264620, at *3 (S.D.W. Va. Mar. 29, 2017) (excluding the alternative-procedures opinion testimony of Dr. Goodyear because "alternative procedures/surgeries do not inform the issue of whether an alternative design for a product exists")).

Ethicon acknowledges that both *Mullins* and *In re: Ethicon* were decided in the context of whether opinion testimony of an alternative surgical procedure is relevant to prove a claim for design defect. But the rule of law followed in these decisions applies equally here to Dr. Moore's opinion that the *surgical technique* for implanting the TVT-O is a defect in the *design* of the TVT-O because a surgical technique is not a product design. *See Bogle v. Sofamor Danek Grp., Inc.*, No. 95-8646, 1999 WL 1132313, at *4 (S.D. Fla. Apr. 9, 1999) (emphasizing that the expert's "testimony fails to identify any particular defect *with the product*. He testified that the design of the screw made it difficult to utilize, that only the most skilled surgeons could implant

it with any degree of success, that if he were designing a pedicle screw he would design it differently . . . . The Court is not persuaded that such testimony identifies a defect in the product, rather, at the most it identifies that it is a product reserved to a top-rate surgeon" (emphasis added)); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 256 (E.D.N.Y. 1999) (granting summary judgment on design-defect claim where expert focused on surgical technique and noninstrumental spinal repair, not a defect in the product itself).

And because a surgical technique is not a product design, as shown through this Court's rulings that evidence of alternative surgical procedures cannot support a claim for design defect, Dr. Moore's criticisms of the surgical technique for implanting the TVT-O are irrelevant to Plaintiff's claim for design defect.

CONCLUSION

For these reasons, Ethicon asks this Court to grant its Motion to Exclude the General-Causation Testimony of Robert D. Moore, D.O. consistent with the arguments raised in its earlier Wave briefing and the supplemental arguments raised here.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on August 15, 2017, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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